

Claim Amendments

This listing of claims will replace all versions, and listings, of claims in the application claims as follows.

Listing of Claims

Claims 1-18. (Canceled)

Claim 19. (Currently Amended): A process for the preparation on an industrial scale of ~~an aqueous suspensions~~ suspension comprising particles of an active ingredient for use as ~~a pharmaceutical formulations~~ formulation for inhalation by nebulization, which comprises:

in a turboemulsifier apparatus comprised of a circular container having a base with an opening therein which receives a turbine device and which contains an aqueous solution, equipped with a vacuum pump, and a loading hopper, which contains a sterile micronized active ingredient, connected to said turbine by a conduit:

- a) ~~operating said turbine containing an aqueous solution and~~ applying a vacuum to the turboemulsifier;
- b) ~~thereby drawing~~ loading the sterile micronized active ingredient ~~by vacuum~~ into the aqueous solution to form a dispersion of the micronized active ingredient; and
- c) stirring and homogenizing the micronized active ingredient in the aqueous suspension by operating the turbine, wherein the micronized active ingredient is loaded in the aqueous solution through the turbine, and whereby the median volumetric diameter of 90 % of the suspended particles of the active ingredient is less than 8 micron and that of at least 50 % ranges from 2 to 3.5 micron.

Claim 20. (Previously Presented): The process as claimed in claim 19, wherein the homogenized suspension is distributed into containers.

Claim 21. (Previously Presented): The process as claimed in claim 19, wherein the aqueous solution contains additives or excipients selected from the group consisting of wetting, stabilizing, isotonic and buffering agents.

Claim 22. (Previously Presented): The process as claimed in claim 19, wherein the micronized active ingredient is a corticosteroid.

Claim 23. (Previously Presented): The process as claimed in claim 19, wherein the aqueous solution has been sterilized by heat or filtration.

Claim 24. (Previously Presented): The process as claimed in claim 22, wherein the micronized corticosteroid is sterilized by irradiation or by heat.

Claim 25. (Previously Presented): The process as claimed in claim 22, wherein the micronized corticosteroid is beclomethasone dipropionate which is sterilized by being subjected to gamma radiation.

Claim 26. (Previously Presented): The process as claimed in claim 19, wherein the homogenization of the suspension is conducted at a turbine speed ranging from 750 to 4000 rpm for 5 to 60 minutes.

Claim 27. (Previously Presented): The process as claimed in claim 26, wherein the homogenization conditions are a turbine speed ranging from 1600 to 3000 rpm for 20 to 40 minutes.

Claim 28. (Previously Presented): The process as claimed in claim 27, wherein homogenization is achieved at a turbine speed of 2900 rpm for 30 minutes.

Claim 29. (Canceled):

Claim 30. (Previously Presented): The process as claimed in claim 19, wherein said containers are monodose vials.

Claim 31. (Canceled):

Claim 32. (Previously Presented): The process as claimed in claim 19, wherein the turbine is provided with a radial nozzle system.

Claim 33. (Previously Presented): The process as claimed in claim 21, wherein the isotonic agent is sodium chloride.

Claim 34. (Previously Presented): The process as claimed in claim 21, wherein the wetting agent is selected from the group consisting of polysorbate 20 and sorbitan monolaurate.

Claim 35. (Previously Presented)A pharmaceutical formulation for administration by nebulization which contains the homogenized aqueous suspension prepared by the process of claim 19.

Claim 36. (Previously Presented): The pharmaceutical formulation as claimed in claim 35, wherein the active ingredient is a corticosteroid selected from the group consisting of BDP, mometasone furoate, flunisolide, budesonide, fluticasone propionate and ciclesonide.

Claim 37. (Previously Presented): The pharmaceutical formulation as claimed in claim 35, wherein the active ingredient is present in the aqueous suspension at a concentration ranging from 0.01 to 0.1 % w/v.

Claim 38. (Previously Presented): The pharmaceutical formulation as claimed in claim 35, wherein unit dose formulations of the pharmaceutical formulation are pre-formed or produced with the “blow, fill and seal” technology.

Claim 39. (Previously Presented): A pharmaceutical formulation in the form of an aqueous suspension that is to be administered by nebulization, comprising:

as active ingredient, a micronized sterile corticosteroid, wherein the median volumetric diameter of 90 % of the particles is less than 8 μm and wherein 50 % of the particles range in size from 2 to 3.5 μm as determined by a Malvern apparatus.

Claim 40. (Previously Presented): The pharmaceutical formulation as claimed in claim 39, wherein the median volumetric diameter of 90 % of the particles is less than 7 μm and wherein 50 % of the particles range in size from 2.5 to 3 μm .

Claim 41. (Previously Presented): The pharmaceutical formulation as claimed in claim 39, wherein the micronized sterile corticosteroid is beclomethasone dipropionate.

Claim 42. (Currently Amended): The ~~process~~ pharmaceutical formulation as claimed in Claim 41, wherein beclomethasone dipropionate is present in the aqueous suspension at a concentration of 0.04 % w/v.

Claim 43. (Previously Presented): A method of treating lung diseases, comprising:
administering by nebulization the pharmaceutical formulation as claimed in claim 40
by once-a-day administration.

Claim 44. (Previously Presented): The method as claimed in claim 43, wherein the lung disease is asthma or chronic bronchitis.